REMARKS

Claims 3, 4, 8, 9, 11, 19-23, 25-26, 38-42, 74-78, 101-104 and 108 remain in this case.

Applicants appreciate the Examiner's consideration given this case, including a telephone interview between the undersigned and the Examiner on October 30, 2003. Claim 38 was discussed but no agreement was reached regarding the claims.

FORMAL MATTERS

The specification has been objected to for failure to provide proper antecedent basis for claimed subject matter. Paragraph 52 of the specification has been amended in response to this objection. Claim 108 has been amended to depend from a pending claim. Paragraph 56 has been amended to correct a typographical error.

Claims 105, 107, 109 and 110 have been rejected under 35 USC §112, first paragraph, for failure to comply with the written description requirement.

Support for these claims can be found at paragraphs 12, 52 and 55 of the present application and Claim 16 of the parent application, which was incorporated by reference.

- Paragraph 12: ... "The agent and may be, for example, ...within the sleeve interior. The dispensable agent may be selected from a group comprising: anti-inflammatory drugs, anti-thrombotic/anti-platelet drugs, and anti-proliferative drugs. The dispensable agent may be an anti-restenotic agent."

- Paragraph 52: ... "A biologically active agent may also be on inner surface 124B or contained within sleeve interior 124C; such agent may be, for example, coated on the stent or may be captured between the stent and inner surface 124B."

- Paragraph 55: ... "Drug layer 147 may include various types of therapeutic and diagnostic pharmaceuticals including, for example, NO generators, paclitaxel, statins, taxol, heparin in its various forms, i.e., low molecular weights, thienopyridines, glycoprotein IIb/IIIb inhibitors, antiplatelet agents, fibrinolytics, anticoagulants, thrombolytics, abciximab, rapamycin, hirudin, VEGF, Hirulog, ticlopidine and clopidogrel, as well as the biologically active agents listed above."

- Claim 16 of parent A/N 09/740,597 filed December 19, 2000:

16. The covered stent according to CLAIM 1 wherein the drug comprises one or more of the following:

NO generators, paclitaxel, statins, taxol, heparin in its various forms, i.e., low molecular weights, thienopyridines, glycoprotein IIb/IIIb inhibitors, antiplatelet agents, antithrombins, fibrinolytics, anticoagulants, thrombolytics, abciximab, rapamycin, hirudin, VEGF, Hirulog, ticlopidine and clopidogrel.

The specification states that the agent can be within the sleeve interior and that NO generators are among the identified agents. NO generators generate NO in conventional and well-known ways. See, for example, the discussion in the background section of U.S. Patent No. 5,797,887 to Rosen, the discussion of the use of nitroprusside as an NO generator at column 5, line 60-column 6, line 1 of Rosen, and the attachments to the prior amendment.

Accordingly, this rejection under 35 USC §112, first paragraph should be withdrawn.

SUBSTANTIVE MATTERS

Claim 38 has been amended by incorporating the substance of claim 105 and also by clarifying that the inner surface of the material defines the sleeve interior; this clarification is taken from claim 74. Claim 74 has been amended to incorporate the substance of claim 107.

Claims 3, 9, 26, 38-41, 74-77, 101-104 have been rejected as anticipated by Razavi '685. Claims 4, 8, 19-23, 25, 38, 42, 101, 102 have been rejected as being obvious over Zukowski '755 in view of Kropf '849 and Ragheb '904. Claim 78 has been rejected as obvious over Razavi '685 in view of Ragheb '904. Claim 11 has been rejected as being unpatentable over Razavi '685 in view of McNamara '370.

The Cited Art

Razavi U.S. Patent No. 5,676,685 discloses a removable, temporary stent 10 comprising a wire coil 12 enclosed within a biodegradable/bioabsorable coating 14. Coating 14 includes outer and inner layers 16, 18. Outer layer 16 may include various agents (column 3, lines 22-30). Inner layer 18 surrounds a wire coil 12 and is made of a material that can be softened or liquefied when heated to permit wire coil 12 to be pulled out from coating 14 leaving coating 14 in place. "Removal of core wire 12 will of course be accomplished at such time as the stent has served its temporary purpose." Column 2, lines 34-36.

Zukowski International Application Publication WO 97/40755 is directed to a device used to repair defective venous valves. The device is positioned externally around the vein at the site of the defective valve. The device provides an external, constricting force to the vein to partially flatten the vein to an oval shape to help restore proper valve operation. Figures 15-18 show a helical support which "is deformed by compression to assume the transversely elliptical cross-section." Page 9, lines 32-33. Accordingly, the Zukowski publication does not disclose an endoluminal prosthesis because it is used outside, not inside a lumen.

Kropf U.S. Patent No. 4,760,849 discloses a planar blank which can be made into a coil spring useful as a filter for thromboses. The coil spring has apertures to facilitate ingrowth of tissue into the spring material. See column 1, lines 61-63 and column 2, lines 51-55. This reference only discloses a stent. It teaches away from adding a graft material because a stated intention of the invention is to permit tissue ingrowth through the apertures. There is no recognition that the addition of a graft material would be useful or possible.

Ragheb U.S. Patent No. 5,873,904 discloses a medical device 10 including a structure 12, typically a vascular stent 12, composed of an elastic/non-elastic, biodegradable/non-biodegradable base material 14, such as stainless steel, nitinol, polymers, etc. Stent 12 is shown to have several layers of materials coated thereon. At least one layer 18 of a bioactive material is on the surface of stent 12. An outer porous layer 20 is on layer 18 to provide controlled release of the bioactive material. A porous/non-porous layer 16 may be used between the bioactive layer 18 and stent 12. A second bioactive layer 22 may be used between porous layer 20 and bioactive layer 18; if so, an inner porous layer 24 may be used between the bioactive layers 18, 22.

McNamara U.S. Patent No. 5,147,370 is cited as disclosing a coil with turns touching one another. However, McNamara discloses a solid metal, specifically nitinol, coil stent having a rectangular cross-section to create tight junctions between the coils "which decreases or prevents ingrowth of invasive cancer tissue through the implanted device or deposition of undesirable blood components on underlying tissue damage to by angioplasty or other procedures used to clear clogged blood vessels." See column 3, lines 40-41 and column 5, lines 21-30. Therefore, it would have been contrary to the teachings of McNamara to create a stent that encourages tissue ingrowth.

1. Claim Rejections-35 USC §102

Claims 3, 9, 26, 38-41, 74-77, 101-104 have been rejected as anticipated by Razavi '685.

Preliminary Remarks

At page 9 of the Office Action, the Examiner states in the first paragraph of the Response to Arguments "Since the structure of Razavi is equivalent to Applicant's embodiment presented in Fig. 5, it must anticipate the claims." This is an improper statement of the law with regard to anticipation, and obviousness for that matter.

At page 9 of the Office Action, the Examiner also states in the first paragraph of the Response to Arguments "Since the Razavi stent is designed analogous to Applicant's, it inherently comprises

open spaces not occupied by the coiled body." This is a simple conclusion not a reason and is completely unsupported by any evidence. First, there is no support for the Examiner's statement that the Razavi stent is designed analogous to Applicant's. Second, Applicant has no idea what the Examiner means by the statement that the Razavi stent is designed "analogous to" Applicant's. Even if it were assumed, for sake of discussion, that the Razavi stent is designed "analogous to" Applicant's, such assumption provides no basis for concluding that it would inherently comprises open spaces not occupied by the coiled body.

The Rejected Claims

Independent apparatus claim 38.

First, the Examiner has taken the positions that Razavi '685 discloses an anti-thrombotic drug associated with material 14 and that "The agent is inherently capable of being dispensable from the sleeve interior through the inner surface and out the outer surface of the sleeve material." However, Razavi '685 teaches that material 14 "may also include quantities of such materials as: anti-thrombotic, anti-platelet, ..." Column 3, lines 22-23. That is, Razavi '685 teaches the incorporation of a drug into the composition of material 14. There is nothing in Razavi '685 disclosing or suggesting the use of:

> "a dispensable, biologically active agent within the sleeve interior, said dispensable agent being dispensable from the sleeve interior, through the inner surface, through the material, out of the outer surface and into a blood vessel of a patient."

Rather, in Razavi '685 material 14, used to coat coil 12, may include a biological agent incorporated therein. However, this is not what is claimed. The agent of Razavi '685 is **not** "inherently capable of being dispensable from the sleeve interior through the inner surface" because Razavi '685 does not disclose a biologically active agent within a sleeve interior (rather, it is incorporated into material 14) nor does it disclose that the biologically active agent be dispensable from this sleeve interior (there is no suggestion in Razavi '685 to place the agent within a sleeve interior), through the inner surface (the agent of Razavi '685 is incorporated into material 14 and therefore would not pass through the inner surface of material 14), through the material and out of the outer surface and into a blood vessel. There is no suggestion or reason to modify the device shown in Razavi '685 to arrive at this presently claimed structure.

Second, the Examiner is taking the position that material 14 forms a coiled sleeve. Applicant disagrees that material 14 could be characterized as a sleeve as that term is commonly understood. "1. The part of a garment that covers all or part of the arm. 2. Any encasement or shell into which a piece of equipment fits." *The American Heritage Dictionary of the English Language, New College Edition,*

Houghton Mifflin Company, 1976. Material 14 may be characterized as coating or layer, but not a sleeve.

Third, even assuming for sake of discussion that any coating could be considered a sleeve, there is no anticipation by Razavi '685 because (1) the sleeve of Razavi '685 is completely filled with the stent is so there is no room for an agent, and (2) the agent of Razavi '685 is incorporated into outer layer 16 (the sleeve) not within the sleeve interior, which is defined by the inner surface of the material. It would not have been obvious to modify Razavi '685 to add an agent dispensable from the sleeve interior, through the inner surface of the sleeve, through the sleeve material and out of the outer surface because the agent of Razavi '685 is incorporated into outer layer 16 (the sleeve).

Accordingly, claim 38 is allowable over Razavi '685.

Dependent **apparatus claims 101, 102**. Claims **101 and 102** (parent: claim 38) more specifically define the open aspects of the sleeve interior to further distinguish the invention over the cited art. See figure 3A and page 11, line 30-page 12, line 2. There is nothing in Razavi '685 suggesting that the prosthesis include a sleeve interior comprising "regions occupied by the coiled body and open spaces not occupied by the coiled body" (claim 101) nor a sleeve interior which "is oversized relative to the coiled body so to loosely contain the coiled body" (claim 102). At page 3 of Office Action, sixth line from the bottom, the Examiner states "See Fig. 2 showing that the coil 12 is surrounded by material 14 and can be considered to loosely contain the coiled body." However, there is absolutely no support for this conclusory statement. Accordingly, claims 101 and 102 are allowable over the cited art for these additional reasons.

Independent method claim 74.

First, Examiner has taken the position that Razavi '685 discloses an anti-thrombotic drug associated with material 14 and that "The agent is inherently capable of being dispensable from the sleeve interior through the inner surface and out the outer surface of the sleeve material." However, Razavi '685 teaches that material 14 "may also include quantities of such materials as: anti-thrombotic, anti-platelet, ..." Column 3, lines 22-23. That is, Razavi '685 teaches the incorporation of a drug into the composition of material 14. There is nothing in Razavi '685 disclosing or suggesting:

> delivering a coiled prosthesis to a target site inside a blood vessel of a patient, ... the prosthesis comprising a coiled body ..., a coiled sleeve of material ..., and a dispensable, biologically active agent within the sleeve interior;...
>
> releasing the agent into the blood vessel, the agent passing from the interior, through the material and into the blood vessel.

Rather, in Razavi '685 material 14 is used to coat coil 12 and may include a biological agent incorporated therein. However, this is not what is claimed. The agent of Razavi '685 is **not** "inherently capable of being dispensable from the sleeve interior through the inner surface" because Razavi '685 does not disclose or suggest delivering a coiled prosthesis comprising a biologically active agent within a sleeve interior (rather, it is incorporated into material 14). Nor does Razavi '685 disclose releasing the biologically active agent from this sleeve interior (there is no suggestion in Razavi '685 to place the agent within a sleeve interior), through the material and into the blood vessel. Therefore, Razavi '685 does not suggest the coiled prosthesis delivering step with the recited placement of the agent nor the agent releasing step with "the agent passing from the interior, through the material and into the blood vessel."

Second, the Examiner is taking the position that material 14 forms a coiled sleeve. Applicant disagrees that material 14 could be characterized as a sleeve as that term is commonly understood. "1. The part of a garment that covers all or part of the arm. 2. Any encasement or shell into which a piece of equipment fits." *The Amerian Heritage Dictionary of the English Language, New College Edition*, Houghton Mifflin Company, 1976. Material 14 may be characterized as coating or layer, but not a sleeve.

Third, even assuming for sake of discussion that any coating could be considered a sleeve, there is no anticipation by Razavi '685 because (1) the sleeve of Razavi '685 is completely filled with the stent is so there is no room for an agent, and (2) the agent of Razavi '685 is incorporated into outer layer 16 (the sleeve) not within the sleeve interior, which is defined by the inner surface of the material. It would not have been obvious to modify Razavi '685 so that the agent passes from the sleeve interior, through the sleeve material and out of the outer surface because the agent of Razavi '685 is incorporated into outer layer 16 (the sleeve) so that the agent of Razavi '685 simply passes from the material and out of the outer surface; the agent of Razavi '685 would not pass from the sleeve interior.

Accordingly, claim 74 is also allowable over Razavi '685.

2. Claim Rejections-35 USC §103

Claims 4, 8, 19-23, 25, 38, 42, 101, 102 have been rejected as being obvious over Zukowski '755 in view of Kropf '849 and Ragheb '904.

Independent apparatus claim 38. First, Zukowski '755 is directed to a device used to repair defective venous valves. The Zukowski '755 device is positioned externally around the vein at the site

of the defective valve. The Zukowski '755 device provides an external, constricting force to the vein to partially flatten the vein to an oval shape to help restore proper valve operation. The Examiner's position that "Clearly, the support device [of Zukowski '755] is capable of being used for inside a blood vessel" is completely unsupported and contrary to the evidence of record. Accordingly, one of ordinary skill in the art would not look to Zukowski '755 when faced with designing a device for use in a blood vessel. **Second**, there is nothing in the cited art disclosing or suggesting the use of:

> "a dispensable, biologically active agent within the sleeve interior, said dispensable agent being dispensable from the sleeve interior, through the inner surface, through the material, out of the outer surface and into a blood vessel of a patient."

Any agent dispensable from the device of Zukowski '755 would necessarily be dispensed from the material, through the inner surface of the device and to the outer surface of a blood vessel, substantially the opposite of what is claimed. Therefore, claim 38 is allowable over the cited art.

Dependent **apparatus claim 8**. Claim 8 (parent: claim 38) recites that the body has side members and connecting cross members. Kropf '849 discloses a solid metal stent having apertures to permit tissue ingrowth through the apertures. Therefore, Kropf '849 teaches away from the suggested combination of Kropf '849 and Zukowski '755 because covering of the stent of Kropf '849 with the material of Zukowski '755 could hinder or prevent the desired tissue ingrowth. In addition, there is nothing in Zukowski '755 suggesting that the additional structural characteristics provided by the ladder-type stent of Kropf '849 would have been useful or desirable. Accordingly, claim 8 is allowable over the cited art.

Dependent **apparatus claim 22**. Claim 22 (parent: claim 38) recites that at least half of the first agent is dispensable prior to the start of dispensing of the second agent; Ragheb '904 separates bioactive layers 18, 22 with a porous layer 24 so that the agent in bioactive layer 18 will start being dispensed when any portion of porous layer 24 is exposed. The Examiner's position is that "it would have been an obvious matter of design choice to modify the ability of the stent to release at least half of a first agent before the second is released, since applicant has not disclosed that using any set amount of one over the another provide any advantage, or solves a stated problem, or is used for any particular purpose." Applicant disagrees for at least two reasons. First, paragraph 56 of the application states:

> "In some situations it may be desirable to make the prosthesis in a manner so that at least first and second biologically active agents are carried by the prosthesis and released in a manner so that at least some of the first agent, for example at least half, is released prior to the start of the release of the second agent. This can be accomplished in several ways. A protective coat 143 may be placed between layers of the biologically active agent. The first agent may be applied over the second agent to cover, and thus initially prevent the release of,

the second agent. One or both of the agents may be encapsulated in biodegradable coverings so to be released only after a period of time."

Therefore, the application provides a basis upon which, for example, at least half of the first agent is released prior to the start of the release of the second agent. There is no requirement in the patent law that a specific situation be specified for this delay. Second, the Examiner's position is a conclusion, not a reason, and therefore an improper basis upon which to reject the claim. The following is quoted from *Ex parte* William R. Garrett, appeal number 580-81, PTOBI 30 September 1986 (copy attached):

"The examiner goes on to say at page 5 of the answer that,

> "Furthermore, wear blades having parallel sides are notoriously well known in the prior art and one of ordinary skill in the art would, through routine engineering design choice, elect to provide a borehole contacting apparatus with blades having parallel sides."

Since this "prior art" has not been identified and is not before us, we will not comment upon it.

... "The examiner's assertion at page 4 of the answer that the proposed modification would have been "an obvious matter of engineering design choice well within the level of skill of one of ordinary skill in the art" is a conclusion, rather than a reason.

Accordingly, the rejection of claims ... is reversed."

As in *Ex parte* Garrett, the Examiner's position is a conclusion, not a reason, and therefore is not a proper basis for rejecting claim 22. Therefore, Ragheb '904, as well as the other art a record, fails to teach or suggest the timing of the dispensing of the agents as specified in claim 22 so that claim 22 is allowable.

Dependent **apparatus claim 25**. Claim 25 (parent: claim 38) recites that the porous material has an inner surface that is substantially impervious to the passage of blood therethrough; this aspect is absent from the cited art. There is no factual support for the Examiner's position that the inner surface of the porous material of Zukowski '755 is inherently impervious to blood. In addition, because the device of Zukowski '755 is used outside a blood vessel to aid the functioning of a malfunctioning venous valve within the blood vessel, there would have been no apparent reason to make the inner surface of the device of Zukowski '755 impervious to the flow of blood. Therefore, claim 25 is allowable over the cited art.

Independent method claim 74.

First, as mentioned above, Zukowski '755 is directed to a device used to repair defective venous valves. The device is positioned externally around the vein at the site of the defective valve. The device provides an external, constricting force to the vein to partially flatten the vein to an oval shape to help restore proper valve operation. The Examiner's position that "Clearly, the support device

[of Zukowski '755] is capable of being used for inside a blood vessel" is completely unsupported and contrary to the evidence of record. Accordingly, one of ordinary skill in the art would not look to Zukowski '755 when faced with designing a method for delivering a biologically active agent to a target type inside a blood vessel.

Second, claim 74 recites delivering the coiled prosthesis to target site within a blood vessel (as opposed to structure of Zukowski '755 being positioned on the outside a vein) and radially expanding the prosthesis to press against the wall of the blood vessel (as opposed to radially contracting the device of Zukowski '755). More specifically, there is nothing in Zukowski '755 disclosing or suggesting the steps of:

> "delivering a coiled prosthesis to a target site inside a blood vessel of a patient, ... the prosthesis comprising ... a dispensable, biologically active agent within the sleeve interior;
>
> radially expanding the prosthesis from the radially-contracted state to a radially-expanded state so to press the prosthesis against the wall; and
>
> releasing the agent into the blood vessel, the agent passing from the interior, through the material and into the blood vessel.

Rather, the structure of Zukowski '755 surrounds the blood vessel and radially contracts so that any delivery of an agent would pass from the material and into the interior of the device for application to the outer surface of the blood vessel. This is substantially the exact opposite of what is being claimed.

Therefore, claim 74 is allowable over the cited art.

3. Claim Rejections-35 USC §103

Claims 105 and 107, which have been incorporated into Independent **Claims 38 and 74,** were rejected under 35 USC 103 (a) is being unpatentable over Razavi '685 in view of Hanson '352. Claims 38 and 74 are allowable for the following additional reasons.

Preliminary Remarks

a) The latest office action improperly ignores all the factual evidence of record regarding the novelty of using NO generators within the sleeve.

b) The combination of Razavi and Hanson '352 would not result in an NO generator, or any other agent, within the sleeve interior because the "sleeve" of Razavi is completely filled with the stent so there is no room for an agent within the sleeve interior and no open regions within the sleeve interior.

c) The following references to Exhibits are to Exhibits filed with the prior amendment mailed July 30, 2003 and filed on August 6, 2003.

Rejected Claims 105/38 and 107/74

Independent apparatus claim 38 recites in part that the agent comprises NO created within the sleeve interior by an NO generator.

It has been found that nitric oxide (NO) is useful to reduce restenosis. See Exhibit A, John B. Cooke MD PhD, Nitric Oxide and Restenosis, A Report For Vascular Architects, Sept. 16, 2002. At room temperature NO is a gas. NO has, however, a short half-life in the body. The testing discussed at Exhibit B, Junghan Yoon, et al, Local Delivery of Nitric Oxide from an Eluting Stent to Inhibit Neointimal Thickening in a Porcine Coronary Injury Model, Yonsei Med J, Vol. 43, No. 2, pp.242-251, 2002, discloses that coating stents with an NO generator incorporated into a polymer was not an effective method for delivery of NO. "However, this sodium nitroprusside-eluting stent failed to reduce chronic neointima thickening in the porcine coronary stent injury model." Exhibit B, page 250. It is believed that the reason for this ineffectiveness in preventing restenosis is due to the manner of the conventional delivery of NO: coating a metal stent with an NO generator.

In contrast, applicants have found through experimentation that a prosthesis, for use inside a blood vessel, made according to claim 38 (Exhibit C, aSpire® covered stent Product Literature) released NO at a therapeutically effective level for over 60 days. It is believed that this extended-length release period is due to the containment of a therapeutically effective amount of the NO generator within a sleeve interior, the sleeve interior being defined by a sleeve of porous material. See Exhibit D (declaration of Kirti Kamdar describing the experiment) and Exhibits E and F (plots of NO vs. time for the experiment).

Applicants are not taking the position that the use of an NO generator per se is new. Rather, the art fails to recognize that there would be an advantage in using an NO generator within the interior of a sleeve of porous material as presently claimed. The evidence of record, discussed above, teaches away from coating stents with an NO generator (because it is ineffective). Further, there is nothing in the art that teaches or suggests using a biologically active agent comprising NO created within the sleeve interior by an NO generator, the agent being "dispensable from the sleeve interior, through the inner surface, through the material, out of the outer surface and into a blood vessel of a patient." By virtue of placing the NO generator within the sleeve interior, a therapeutically effective amount of NO

generated by the NO generator can be delivered to the blood vessel over a therapeutically effective time period. The art simply lacks any recognition of this aspect of the invention.

Independent method claim 74 recites that the delivering step comprises choosing an agent comprising NO created within the sleeve interior by an NO generator.

It has been found that nitric oxide (NO) is useful to reduce restenosis. See Exhibit A, John B. Cooke MD PhD, Nitric Oxide and Restenosis, A Report For Vascular Architects, Sept. 16, 2002. At room temperature NO is a gas. NO has, however, a short half-life in the body. The testing discussed at Exhibit B, Junghan Yoon, et al, Local Delivery of Nitric Oxide from an Eluting Stent to Inhibit Neointimal Thickening in a Porcine Coronary Injury Model, Yonsei Med J, Vol. 43, No. 2, pp.242-251, 2002, discloses that coating stents with an NO generator incorporated into a polymer was not an effective method for delivery of NO. "However, this sodium nitroprusside-eluting stent failed to reduce chronic neointima thickening in the porcine coronary stent injury model." Exhibit B, page 250. It is believed that the reason for this ineffectiveness in preventing restenosis is due to the manner of the conventional delivery of NO: coating a metal stent with an NO generator.

In contrast, applicants have found through experimentation that delivering a biologically active agent, comprising NO created by an NO generator, to a target site inside a blood vessel by releasing the agent from the interior of a coiled sleeve of material, through the material and into the blood vessel according to claim 74, released NO at a therapeutically effective level for over 60 days. It is believed that this extended-length release period is due to the containment of a therapeutically effective quantity of the NO generator within the sleeve interior. See Exhibit D (declaration of Kirti Kamdar describing the experiment) and Exhibits E and F (plots of NO vs. time for the experiment).

Applicants are not taking the position that the use of an NO generator per se is new. Rather, the art fails to recognize that there would be an advantage in using an NO generator within the interior of a sleeve of material as presently claimed. The evidence of record, discussed above, teaches away from coating stents with an NO generator (because it is ineffective). Further, there is nothing in the art that teaches or suggests using a biologically active agent comprising NO created within the sleeve interior by an NO generator, the agent being "dispensable from the sleeve interior, through the inner surface, through the material, out of the outer surface and into a blood vessel of a patient." By virtue of placing the NO generator within the sleeve interior, a therapeutically effective amount of the NO generator can be carried by the prosthesis for delivery of a therapeutically effective amount of NO to the blood vessel over a therapeutically effective time period. The art simply lacks any recognition of this aspect of the invention.

4. Claim Rejection-35 USC §103

Claim 11 was rejected under 35 USC 103 (a) as being unpatentable over Razavi '685 in view of McNamara '370.

Dependent **apparatus claim 11**. Claim 11 (parent: claim 38) recites that the adjacent turns touch one another when in the radially-expanded state. Claim 38 recites a coiled sleeve of porous material. In contrast, McNamara is designed to create tight junctions between the adjacent coils to prevent ingrowth of tissue. Therefore, it would have been contrary to the teachings of McNamara to create a stent that encourages tissue ingrowth as could the invention of claim 11. Accordingly, claim 11 is allowable over the cited art.

The dependant claims not specifically referred to above are directed to specific novel subfeatures of the invention and are allowable for that reason as well as by depending from novel parent claims.

In light of the above remarks and amendments to the claims, applicants submit that the application is in the condition for allowance and action to that end is urged. If the Examiner believes a telephone conference would aid the prosecution of this case in any way, please call the undersigned at (650) 712-0340.

Respectfully submitted,

Dated: 22 January 2004

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Attached: *Ex parte* William R. Garrett, appeal number 580-81, PTOBI 30 September 1986

Exhibits: The following Exhibits have been filed with the prior amendment mailed July 30, 2003 and filed on August 6, 2003.

A: John B. Cooke MD PhD, Nitric Oxide and Restenosis, A Report For Vascular Architects, Sept. 16, 2002.

B: Junghan Yoon, et al, *Local Delivery of Nitric Oxide from an Eluting Stent to Inhibit Neointimal Thickening in a Porcine Coronary Injury Model,* Yonsei Med J, Vol. 43, No. 2, pp.242-251, 2002.

C: aSpire® covered stent Product Literature

D: Declaration of Kirti Kamdar

E: Elution Data (the results of Groups 1 and 2 plotted separately)

F: T 1/2 (single plots for Group 1 and 2 plus a best-fit curve)

Art Unit 245 MAILED Paper No. 13

SEP 30 1986

PAT. & T.M. OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

Appeal No. 580-81 dm

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte William R. Garrett

- - -

Application for Patent filed July 29, 1981, Serial No. 287,769, which is a Continuation-in-Part of Serial No. 187,350, filed September 15, 1980. Fixed-Contact Stabilizer.

Frank S. Vaden, III et al. for appellant.

Primary Examiner - Stuart S. Levy
Examiner - D. Werner.

Before Henon, Craig and Lindquist, Examiners-in-Chief.

Lindquist, Examiner-in-Chief.

This appeal is from the final rejection of claims 1 through 4, 7 through 10, 21 through 25, 27, 31 through 33, 44 through 50 and 52 through 56. Of the remaining claims in this application, claims 5, 6, 28, 29 30 and 51 stand withdrawn from consideration and claims 11

through 20, 26, and 34 through 43 have been allowed by the examiner.

The invention pertains to a drill string stabilizer which is apparent from a reading of illustrative claim 44, reproduced below.

44. Borehole apparatus comprising

a tubular body having a flow axis,

said body having a plurality of equiazimuthally spaced substantially parallel sides [sic, sided?] slots each extending in a direction having at least a paraxial component, and

blade means received in each slot making an interference fit with the sides of the slot.

The references cited by the examiner are as follows:

Dixon et al. (Dixon)	3,680,647	Aug. 1, 1972
Bassinger	4,106,823	Aug. 15, 1978

All the claims at bar stand rejected under 35 U.S.C. 103 as obvious. As evidence of obviousness, the examiner cites Bassinger as to claims 1 through 4, 21 through 25, 27, 44 through 50 and 52 through 56 and adds Dixon as to claims 7 through 10 and 31 through 33.

Reference is made to the brief and the answer for the respective positions of the appellant and the examiner.

OPINION

We note in passing that "said uppermost blade" in claims 2, 9, 22 and 33 lacks an antecedent basis. As noted in claim 44 reproduced above, it appears to us that "sides" should be "sided" to conform with the interpretation given the claim by the appellant and the examiner. That is to say, the appellant and the examiner have construed claim 44 as calling for plural slots each having substantially parallel sides, and so will we. The

locking means at the ends of the blade components of claim 53 do not appear to be capable of locking with adjacent components and the slot ends.

We have considered the rejection of the claims at bar under section 103 in light of the respective positions of the appellant and the examiner and conclude that it cannot be sustained.

All the claims at bar require that the pockets or slots in the stabilizer body have substantially parallel sides. As disclosed in the paragraphs bridging pages 15 and 16 and pages 20 and 21 of the specification, the appellant means by this language that the pocket or slot sides are at least within a few thousands of an inch of being precisely parallel.

The examiner's contention to the contrary at the bottom of page 4 and the top of page 5 of the answer notwithstanding, sidewalls 21 and 22 of the wear blade supporting grooves of Bassinger are not substantially parallel; each is inclined at an angle of 30° with respect to the other.

The examiner goes on to say at page 5 of the answer that,

> "Furthermore, wear blades having parallel sides are notoriously well known in the prior art and one of ordinary skill in the art would, through routine engineering design choice, elect to provide a borehole contacting apparatus with blades having parallel sides."

Since this "prior art" has not been identified and is not before us, we will not comment upon it.

With respect to the proposed modification of the Bassinger structure by further coupling the wear blades to the stabilizer body with screws or bolts of the type

disclosed by Dixon, the examiner has not presented any line of reasoning as to why the artisan would have been motivated to so modify the Bassinger structure, and we know of none. The examiner's assertion at page 4 of the answer that the proposed modification would have been "an obvious matter of engineering design choice well within the level of skill of one of ordinary skill in the art" is a conclusion, rather than a reason.

Accordingly, the rejection of claims 1 through 4, 7 through 10, 21 through 25, 27, 31 through 33, 44 through 50 and 52 through 56 under 35 U.S.C. 103 is reversed.

REVERSED

Paul J. Henon, Jr.
Examiner-in-Chief

Jerry D. Craig
Examiner-in-Chief

William F. Lindquist
Examiner-in-Chief

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